K041477

DEC - 9 2004

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510(k) SUMMARY

1. TRADE NAME: PathFinder Image Guided Surgical Localiser

2. COMMON NAME: Image Guided Surgical Localiser

3. CLASSIFICATION NAME: Instrument Stereotaxic per CFR 21, Section 882.4560

4. PREDICATE DEVICE: K991081 Frameless Neuromate (ISS Inc, Palo Alto, California)

5. DESCRIPTION: A stereotaxic system with a computer-controlled mechanical arm for spatial positioning and orientation of an instrument holder or tool guide. Guidance is based on a pre-operative plan developed with three-dimensional imaging software, and utilises CCD camera registration based on fiducial markers. The system is intended for use by neurosurgeons to guide standard neurosurgical instruments.

6. INTENDED USE: An image-guided computer-controlled mechanical arm intended to be used in a neurosurgical operating room for the spatial positioning and orientation of an instrument holder or tool guide to be used by surgeons to manually guide standard neurosurgical instruments, under a surgeon-developed carefully prepared stereotaxic plan. The mechanical arm does not contact the patient.

7. INDICATION FOR USE: Stereotaxic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon manually to guide standard neurosurgical instruments.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:
   a. No substantive change in performance, function, method of operation, design principles or method of manufacture between this device and the predicate device. The system and its components have been used in the medical device industry for similar applications, with no record of any patient problems or adverse reactions.

b. The device has been designed, built and independently tested for compliance with international safety and EMC standards.
c. The function and use of the device are no different from that of the predicate device and other similar devices in the marketplace.

Name of contact for this summary: Dr Patrick A. Finlay, Managing Director, Armstrong Healthcare Limited. Contact details as shown above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2004

Mr. Patrick A. Finlay
Managing Director
Armstrong Healthcare Limited
Knaves Beech Business Centre
Loudwater, High Wycombe
HP 10 9QR
United Kingdom

Re: K041477
Trade/Device Name: Pathfinder Image-Guided Surgical Localiser
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: September 22, 2004
Received: September 24, 2004

Dear Mr. Finlay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041477

Device Name: PathFinder Image Guided Surgical Localiser

Indications For Use:

Stereotaxic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon manually to guide standard neurosurgical instruments.

Prescription Use _YES_ AND/OR Over-The-Counter Use_NO_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041477